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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,154	09/19/2003	Bryan Windus-Smith	DDI-5016	8222
27777	7590	03/05/2007	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			REYNOLDS, STEVEN ALAN	
			ART UNIT	PAPER NUMBER
			3728	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		03/05/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No. 10/666,154	Applicant(s) WINDUS-SMITH ET AL.	
	Examiner Steven Reynolds	Art Unit 3728	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>9/19/03, 1/13/05, 7/11/06, 2/12/07</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Upon further consideration, claims 1-12 are rejoined with claims 13-18 as the search for the two inventions was not burdensome on the examiner. The restriction requirement has been withdrawn. Claims 1-18 are pending in this action.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 5 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The only mention of ribs is in paragraph 72 of the specification, wherein the ribs are disclosed as being disposed internally in the medical device package, not on the minor cap member as claimed. To examine the claim on its merits, it is presumed that the ribs are disposed on the main cap member.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2, 4-9, 11-13 and 15-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Magney (US 4,180,162). Magney discloses a medical device package comprising a main cap member (box 10 in combination with cover 14) with a cavity therein, the main cap member including: a proximal end; and a distal end; and a minor cap member (18); a connector (scalpel handle 31); wherein the cavity has a cavity opening at the proximal end of the main cap member; the cavity is configured to receive, and to securely and removably retain, a medical device (blade 21), and the minor cap member is capable of sealing the cavity opening once the medical device has been received in the cavity; the connector is configured to engage the medical device during removal of the medical device from the cavity and includes a strip engaging element (boss 33) capable of contacting electrical contacts; the main cap member includes at least one lateral channel (channel between 17 and 26) and wherein the medical device is securely and removably retained by a friction fit between the medical device and the at least one lateral channel; the main cap member is capable of receiving and removably retaining an integrated medical device that includes electrical contacts; the main cap member includes ribs (ribs protruding from side walls 11 at end wall 12a on either side of the opening in the end wall in which the flap 18 attaches to) that seal the cavity opening; the minor cap member is breachable; the minor cap member is capable of permanent attachment to the medical device; the main cap

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member further includes a distal end cavity capable of disabling the medical device; and the connector is capable of breaching the minor cap member.

Further regarding claims 13 and 15-18, Magney discloses the method for extracting a medical device including the steps of breaching the minor cap member with the connector such that at least a portion of the connector has entered the cavity of the medical device cavity; engaging the medical device with the connector; extracting the connector and engaged medical device from the cavity of the medical device package; subsequently inserting the connector and engaged medical device into a cavity of the medical device package to a second position whereby the medical device is disabled from subsequent use; the inserting step includes inserting the engaged medical device into the distal end cavity of the main cap member; disengaging the connector from the disabled medical device; and withdrawing the connector from the medical device package.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Magney (US 4,180,162) in view of Vidal et al. (US 4,903,390). As described above, Magney discloses the claimed invention except for the directional marker on the main cap member. However, Vidal et al. teaches a medical device package comprising a main cap member including an arrow (61) for the purpose of indicating that the scalpel is to be inserted with the cutting edge of the blade extending upwardly. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the main cap member of Magney with an arrow as taught by Vidal et al. to indicate to the user which direction to insert the medical device into the cavity.

6. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Magney (US 4,180,162) in view of Newman et al. (US 2002/0143352). As described above, Magney discloses the claimed invention except for the specifics of the connector. However, Newman et al. teaches a connector (scalpel handle) comprising a shield (40) slidably mounted to the scalpel to prevent inadvertent access to the blade, including arrows (28) on the scalpel for the purpose of visual indication to the user of the direction in which the shield should be moved. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the connector (scalpel handle) of Magney with the shield and arrows as taught by Newman et al. in order to shield the medical device (blade) when not in use.

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7. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Magney (US 4,180,162) in view of Charlton (US 2003/0036200). As described above, Magney discloses the claimed invention except for the specifics of the medical device. However, Charlton teaches a medical device (test sensor 120) comprising a tissue penetration member and a test strip for the purpose of collecting and testing a sample of blood. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the medical device package of Magney to store the medical device as taught by Charlton in order to safely dispose the used medical device.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Soroff et al. (US 5,938,027), Rastegar et al. (US 6,216,868) and Pollak et al. (US 4,746,016).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven Reynolds whose telephone number is (571)272-9959. The examiner can normally be reached on Monday-Friday 9:00am - 5:00pm.

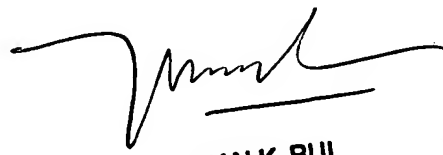
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on (571)272-4562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SR

3/1/07



LUAN K. BUI
PRIMARY EXAMINER